

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION) **MDL 2804**
THIS DOCUMENT RELATES TO:)
Track One Cases) **Case No. 1:17-md-2804**
) **Judge Dan Aaron Polster**
) **OPINION AND ORDER DENYING**
) **MALLINCKRODT'S MOTION FOR**
) **PARTIAL SUMMARY JUDGMENT**
)

Before the Court is Mallinckrodt's Motion for Partial Summary Judgment (**Doc. #: 1907**).

For the reasons set forth below, the Motion is **DENIED**.

* * * * *

Against Mallinckrodt, Plaintiffs assert claims based on two factual theories: (1) fraudulent marketing; and (2) the failure to maintain effective controls against diversion. As to the fraudulent marketing claims, Mallinckrodt seeks partial summary judgment on the claims involving the promotion of its generic opioid products.¹ In addition, Mallinckrodt seeks summary judgment on claims based on its alleged failure to maintain effective controls after 2012. The Court addresses these arguments below.

¹ Mallinckrodt does not seek summary judgment on the claims related to the promotion of its branded opioid products.

I. Legal Standards.

The Court hereby incorporates the legal standards set forth in the Court's Opinion and Order regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, see Doc. #: 2483.

II. Analysis.

A. Fraudulent Marketing of Generic Opioid Products.

Mallinckrodt asserts that, as to its sales of generic opioid products, Plaintiffs have no evidence to support their fraudulent marketing claims. Specifically, Mallinckrodt asserts it does not promote its generic drugs to physicians, but, instead, merely sells these generic medications in competition with other generic manufacturers in the marketplace, based primarily on price, quality, and service. *See* Mkt. Mem. at 3-4 (Doc. #: 1907-2). While Mallinckrodt admits it engaged in promotional activities with respect to its “very few branded opioid products,” it asserts that more than 99.7 percent of its opioid sales were generic medications that it did not promote to physicians. *Id.* at 3. Mallinckrodt asserts that, as to these generic opioid sales, Plaintiffs cannot prevail on their fraudulent marketing claims, because Plaintiffs cannot show Mallinckrodt promoted these products to physicians or, even if it did, that Mallinckrodt did so in a manner that was false or misleading. *See id.* at 1, 4.

Plaintiffs respond with evidence that indicates Mallinckrodt sponsored and distributed misleading “unbranded” promotional materials to encourage the overall prescribing of opioids. *See* Pls. Opp. at 5-10 (Doc. #: 2293). For instance, Plaintiffs point to materials promoted by Mallinckrodt’s C.A.R.E.S. Alliance to provide “educational programs and resources to support responsible prescribing and safe use of opioid analgesics.” Pls. Ex. 28 at 3 (Doc. #: 2295-4)

(C.A.R.E.S. Alliance catalog).² Under the category of “patient tools,” the C.A.R.E.S. Alliance catalog promotes a book entitled “Defeat Chronic Pain Now!” as a resource that “provides patients with groundbreaking strategies for eliminating the pain of arthritis, back and neck conditions, migraines, diabetic neuropathy, and chronic illness.” *Id.* at 13; *see also* Pls. Ex. 27 at 3 (Doc. #: 2295-3) (listing the same book as an example of “Education and Enabling Tools” for patients). Plaintiffs contend the book contains misleading information, including:

- “When chronic pain patients take opioids to treat their pain, they *rarely* develop a true addiction and drug craving.” *Id.* at ECF p. 7 (emphasis added).
- “The bottom line: *Only rarely* does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.” *Id.* (emphasis added).
- “Here are the facts. It is *very uncommon* for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.” *Id.* at ECF p. 9.

Pls. Opp. at 9 (Doc. #: 2293).

By contrast, Plaintiffs’ expert has opined that the rates of opioid misuse following medical use range from *21 to 29 percent*, with opioid addiction risk ranging from eight to 12 percent, *with even higher rates* for individuals who are on high doses of opioids for long periods of time. *See Keyes Rpt.* at 11-16 (Doc. #: 1868-4) (expert report of epidemiologist, Katherine Keyes).³ In light of this conflicting evidence, which suggests that Mallinckrodt, through the C.A.R.E.S. Alliance, promoted the use of opioids generally with misinformation information regarding the rate of addiction, the record presents genuine issues of material fact regarding whether Mallinckrodt

² The C.A.R.E.S. Alliance catalog states: “C.A.R.E.S. Alliance is a service mark of Mallinckrodt Inc.” Pls. Ex. 28, at ECF p. 2 (Doc. #: 2295-4).

³ The Court overruled Defendants’ motion to exclude Keyes’ testimony. *See* Doc. #: 2549.

engaged in misleading promotional activities regarding its sales of generic opioids. Moreover, to the extent Mallinckrodt may have engaged in misleading marketing statements regarding its branded opioid products (that are not subject to the current Motion), there is evidence to suggest – and a factfinder could logically infer – that those statements were intended to and did boost its sales of generic prescriptions as well. On this record, Mallinckrodt has not shown that Plaintiffs have no evidence to support their fraudulent marketing claims regarding its sales of generic opioids. Accordingly, summary judgment is not warranted on this ground.

B. Failure to Maintain Effective Controls After 2012.

Mallinckrodt seeks summary judgment on Plaintiffs' claims that it failed to maintain effective controls after 2012.⁴ This Court has found that, as a matter of law, the Controlled Substance Act and its implementing regulations require registrants to: (1) design and operate a system to disclose to the registrant any suspicious orders; (2) inform the DEA of suspicious orders when discovered by the registrant; and (3) not ship a suspicious order unless due diligence reasonably dispels the suspicion. *See Order on Pls. MSJ re CSA at 15, 18-19 (Doc. #: 2483)* (citations omitted).

Mallinckrodt contends Plaintiffs cannot show that, after 2012, it shipped a single suspicious order to any customer in the *Track One* Counties. *See* Mlkt. Mem. at 5-6 (Doc. #: 1907-2). In denying Defendants' Motion for Summary Judgment on Causation (Doc. #: 2561), the Court rejected this same argument. More specifically, the Court found that, to prevail on these claims,

⁴ Although Mallinckrodt does not explain the significance of 2012, the Court notes that, in a separate motion, Defendants assert all claims based on conduct before October 27, 2012 are time-barred. *See* Defs. MPSJ on Stat. of Lim. (Doc. #: 1896).

Plaintiffs need not identify specific orders that Defendants should not have shipped. *See id.* at 8. Rather, in light of the massive supply of prescription opioids into the *Track One* Counties, combined with evidence of an alleged virtually complete failure by Defendants to maintain effective controls against diversion, a factfinder could reasonably infer such failures were a substantial factor in producing the alleged harm suffered by Plaintiffs. *See id.* The same analysis applies here. Thus, to overcome summary judgment, Plaintiffs need only show evidence sufficient to create a genuine issue of material fact as to whether Mallinckrodt failed to maintain effective controls against diversion. *See id.*

Mallinckrodt asserts Plaintiffs cannot show that, after 2012, it failed to maintain effective controls against diversion. *See* Mlkt. Mem. at 6-8 (Doc. #: 1907-2). Specifically, Mallinckrodt asserts that, since 2010, it has employed a robust anti-diversion program, and Plaintiffs have no expert opinion that, after 2012, its program was deficient. *See id.*

In response, Plaintiffs point to their data mining expert, Lacey Keller, who found the Manufacturer Defendants had both the data and standard data-analytic tools to allow them to determine suspicious prescribing and purchasing patterns that they did not report.⁵ *See* Keller Rpt. at 9-11 (Doc. #: 1914-4). Specifically, Keller reviewed Mallinckrodt's data *through 2017* and determined that: (1) applying various compliance metrics, millions of prescriptions would have been flagged as suspicious, *see id.* at 30; and (2) more than 50 percent of buyers would have been flagged as suspicious, *see id.* at 60.⁶ Further, Keller found thousands of transactions that Mallinckrodt identified as "peculiar" that ended up in the *Track One* Counties. *See id.* at 83-84.

⁵ The Court overruled Defendants' motion to exclude Keller's testimony. *See* Doc. #: 2492.

⁶ Keller examined IQVIA Data, ARCOS Data, and Chargebacks and other sales data. *See* Doc. #: 2492 at 4-5.

In addition, Plaintiffs point to Mallinckrodt’s internal emails which suggest that, after 2012, Mallinckrodt failed to conduct due diligence before releasing suspicious orders. *See, e.g.*, Pls. Ex. 83 (Doc. #: 2300-34) (2013 email, indicating the release of an order that brought the customer’s December monthly volume alone to 29 percent of its total year-to-date orders); Pls. Ex. 86 (Doc. #: 2301-1) (2014 emails, indicating the release of an order that exceeded the total quantity for any customer within that segment for the past 18 months, without inquiry as to whether the increased demand was for one customer or spread across multiple customers); Pls. Ex. 90 (Doc. #: 2301-5) (2016 emails, indicating the release of multiple orders simply based on the distributor’s explanation that there was a “spike [in demand] in the last couple of weeks”); Pls. Ex. 91 (Doc. #: 2301-6) (2016 emails, indicating the release of an order before obtaining the required “documentation” for the suspicious order monitoring files).

Based on this evidence, a jury could reasonably conclude that, after 2012, Mallinckrodt failed to maintain effective controls against diversion, and these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs. *See Order at 8 (Doc. #: 2561)*. Accordingly, Mallinckrodt is not entitled to summary judgment on this ground.

III. Conclusion.

For the reasons stated above, the Court **DENIES** Mallinckrodt's Motion for Partial Summary Judgment (**Doc. #: 1907**).

IT IS SO ORDERED.

/s/ Dan Aaron Polster
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE